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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,032	02/09/2005	Chise Mukaidani	2004 1544A	1374

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EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
09/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,032	MUKAIDANI ET AL.	
	Examiner	Art Unit	
	MARCIA S. NOBLE	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8-10,12-15, 17-21 and 23-33* is/are pending in the application.

4a) Of the above claim(s) *3-6,12-15,19-21 and 23-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-10,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/17/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/8/2008 has been entered. The amendment filed 2/8/2008 has been entered and is under consideration.

Status of Claims

2. Claims 1, 3-6, 8-10,12-15, 17-21, and 23-33 are pending. Claims 3-6, 12-15, 19-21, and 23-33 were previously withdrawn as non-elected subject matter. Claims 1, 8, 10, and 17 are amended and claims 7 and 16 are canceled by the amendment, filed 2/8/2008. Claims 1, 8-10, 17, and 18 are under consideration.

Withdrawn Objections/Rejections

3. a) The objection of claims 7 and 16 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, as set in the Office Action, mailed 11/17/2006 (p. 4, 2nd par), is withdrawn.

b) The rejection of claims 1, 7-10, and 16-18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of proliferating

human hepatocytes comprising transplanting proliferative human hepatocytes into the liver of a uPA-Tg/SCID immunodeficient hepatopathy mouse comprising a homozygous insertion of a uPA-Tg into the genome of a homozygous SCID mouse, administering an effective amount of the complement inhibitor, Futhan, to protect against tissue damage associated with human complement produced by human hepatocytes, proliferating said human hepatocytes in the liver of said mouse, isolating human hepatocytes from the liver of said mouse transplanted with human hepatocytes, and transplanting the human hepatocytes isolated from the liver of said mouse into other uPA-Tg/SCID immunodeficient hepatopathy mice comprising a homozygous insertion of a uPA-Tg into the genome of a homozygous SCID mouse, does not reasonably provide enablement for a method comprising transplanting non-proliferative hepatocytes and does not enable transplanting proliferative human hepatocytes into the liver of an immunodeficient hepatopathy mouse or an immunodeficient hepatopathy mouse administered any complement inhibitor by any method including feeding or a progenitor mouse obtained by mating between an immunodeficient hepatopathy mouse and a decay-accelerating factor (DAF/CD55) transgenic mouse, proliferating said human hepatocytes in the liver of said mouse, isolating human hepatocytes from the liver of said mouse transplanted with proliferative human hepatocytes, and transplanting the human hepatocytes isolated from the liver of said mouse into any other immunodeficient hepatopathy mice, or an immunodeficient hepatopathy mice administered a complement inhibitor or progenitor mice obtained by mating between an immunodeficient hepatopathy mice and a decay-accelerating factor (DAF/CD55)

transgenic mice, does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use/make the invention commensurate in scope with these claims, as set forth in the Office Action, mailed 11/17/2006 (pp. 8-16), is withdrawn.

c) The rejection of claims 10 and 16-18 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth in the Office Action, mailed 8/10/2007 (pp. 12-14), is withdrawn.

d) The rejection of claim 10, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth in the Office Action, mailed 8/10/2007 (pp. 14-15), is withdrawn.

Comment [V1]: Are they? They don't teach how to administer it. Is the art clear on this? Would any route of administration work? If yes, then OK. But I'd include in a WD paragraphe that they don't have descriptive support for feeding Futhan as encompassed by the claims.

Claim Objections

4. Claims 9 and 18 are objected to because of the following informalities: Claims 9 and 18 recite "K8223". However, the specification discloses the hybridoma as “K8233” (see page 43, line 24). Therefore, the recitation in the claims is inconsistent with the disclosure of the specification. Amending the claims to recite the same hybridoma as disclosed in the specification would be remedial, if the specification comprises the correct recitation. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Biological Deposit

5. Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention of claims 8 and 9 appears to employ specific biological matter, Mouse-Mouse Hybridoma K8223 (FERM BP-8334). Since the hybridoma is essential to the claimed invention, they must be obtained by a repeatable method set forth in the specification or otherwise readily available to the public. If the hybridoma are not so obtainable or available, the requirements of 35 U.S.C.§ 112 may be satisfied by a deposit of the hybridoma. The specification does not disclose a repeatable process to obtain the hybridoma and it is not apparent if the hybridoma is readily available to the public. It is noted that Applicant has deposited the hybridoma (p.43, lines 23-28), but there is no indication in the specification of public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over her or her signature and registration number, stating that the specific hybridoma has been deposited under the Budapest Treaty and that the hybridoma will be irrevocably and without restriction or condition released to the public

upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over her or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained I a public depository for a period of 30 years or 5 years after the last request or the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R.§ 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention id directed to M.P.E.P §2411.05, as well as to 37 C.F.R.§ 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the

ATCC has recently been changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

Applicant is cautioned the deposit requirement remains even if the deposit number in the claims is changed to match that disclosed. The reasoning is the same. Claims 8 and 9 require a specific hybridoma, which can only be obtained from applicant.

Comment Regarding Scope of Invention

Upon further consideration, Examiners believes that the claims should not be narrowly limited to Futhan and would be enabled for claims that more broadly recite administering an effective amount of a complement inhibitor to protect against tissue damage associated with human complement produced by the human hepatocytes. Thus, applicant, if they wish, can amend the claims more broadly.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 8-10, 17, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rejected over the use of the trademark, Futhan, in claims 1 and

10. MPEP 2173.05(u) states:

> If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product.

Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. It is suggested applicant delete "Futhan" and insert "an effective amount of a complement inhibitor to protect against tissue damage associated with human complement produced by the human hepatocytes".

Claims 8, 9, 17 and 18 depend upon claims 1 and 10.

7. The claims are free of the prior art. At the time of filing the prior art did not teach or suggest a method for proliferating human hepatocytes, which comprises transplanting proliferative human hepatocytes into the liver of an immunodeficient hepatopathy mouse, administering to the mouse an effective amount of a complement inhibitor to protect against tissue damage associated with human complement produced by the human hepatocytes, and proliferating said human hepatocytes in the liver of said mouse.

Response to Amendment

8. The declaration under 37 CFR 1.132 filed 2/8/2008 is sufficient to overcome the rejection of claims 1, 7-10, and 16-18 based upon 112, 1st paragraph enablement rejection. However, other 112, 1st paragraph issues still remain.

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble

/Peter Paras, Jr./

Supervisory Patent Examiner, Art Unit 1632